United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Microbiological Data Program

SOP No.: MDP-ADMIN-06B		Page 1 of 7
Title: Laboratory Quality Assurance Units (QAUs)		
Revision: 01	Replaces: 08/15/03	Effective: 05/01/06

1. Purpose

To establish requirements for uniform quality assurance units (QAUs) within the laboratories participating in the USDA/AMS Microbiological Data Program (MDP).

2. Scope

This Standard Operating Procedure (SOP) shall be followed by all laboratories conducting microbiological studies for MDP, including support laboratories conducting non-routine activities that may impact the program.

3. Outline of Procedure

4. References

- MDP Federal/State Meeting, Arlington, VA, May 15-16, 2003
- U.S. EPA, Quality Assurance Unit, 40 CFR part 160.35, July 1, 2005

5. Specific Procedures

5.1. Description

5.1.1. Each laboratory shall have a QAU which shall be responsible for monitoring MDP studies to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the plans and SOPs issued by USDA/AMS and by the laboratory.

5.1.2. The QAU shall be entirely separate from and independent of personnel engaged in the technical direction and conduct of the studies. The QAU shall report to non-technically involved laboratory management such as the laboratory director or the

Administrative Manager. The Technical Program Manager (TPM) is considered to be involved in the technical direction and conduct of the studies, and therefore, may not direct the QAU.

5.1.3. The QAU may consist of one or more personnel of suitable qualifications.

5.1.4. For those participants where there are two or more field facilities under a common administration there only needs to be a single QAU.

5.1.5. The QAU shall conduct audits and maintain records appropriate to MDP studies.

5.2. Files and Records

5.2.1. The QAU shall maintain a copy (electronic or printed) of the MDP annual, semi-annual, or quarterly plan including the schedule of samples, organisms, and commodities to be tested.

5.2.2. The QAU shall ensure that project status reports (e.g., progress on validation studies or annual SOP review) are prepared. The QAU shall maintain a copy of the report.

5.2.3. A schedule of audits and audit report submissions shall be maintained. This shall include the dates audits were made, the dates findings were reported to management, the Administrative Manager, the TPM, the USDA/AMS Technical Director, and the response(s) including any corrective actions taken.

5.2.4. The QAU shall maintain copies of all SOPs pertaining to MDP studies in which the laboratory is involved and for which the unit is responsible. The documents shall include as a minimum requirement: all USDA/AMS SOPs, all internal laboratory SOPs, analytical methods utilized for sample analysis, and any other documents required (in writing) to be maintained by USDA/AMS.

5.2.5. The QAU may also maintain whatever documentation is deemed necessary to show compliance with USDA/AMS requirements.

5.2.6. The QA documents shall be maintained in a secure manner with reasonable environmental protection from deterioration. The duration shall be in compliance with USDA/AMS data archiving requirements and the individual laboratory records policy, whichever is more stringent.

5.3. Reports

5.3.1. The QAU shall prepare and submit to the Monitoring Programs Office (MPO) semi-annual updates based on calendar year summarizing QA issues. Updates shall be submitted within 30 days after the completion of the reporting period and should include the status of the following:

5.3.1.1. Progress on method validations

5.3.1.2. Problematic trends and corrective action(s) taken

5.3.1.3. SOPs, new and revised, titles and status specified (refer to sections 5.8 and 5.9)

5.3.1.4. Internal audit summary, including dates, subjects audited (refer to section 5.5), and unresolved issues

5.3.1.5. Documentation of corrective action taken based on program proficiency testing results

5.3.1.6. Changes to methodology

5.3.1.7. Staff changes

5.3.1.8. Miscellaneous QA issues

5.4. Data Review and Transmission

5.4.1. The QAU shall review all data packages as one of the final steps prior to submission to USDA/AMS. The QAU review shall be documented. Each laboratory shall, in an internal SOP, establish the proper procedures for data review which shall include the stipulation that after the QAU review of a data package, that data may not be changed by any lab personnel unless as a response to comments/concerns/recommendations by the QAU.

5.4.2. The QAU shall notify the TPM of any recurring data errors or problems, and recommend corrective action as necessary.

5.5. Audits

5.5.1. The QAU shall audit the operations of each laboratory for which it has responsibility at intervals adequate to ensure the integrity of MDP studies. Each segment or phase of the MDP's laboratory operations shall be audited at least once per year.

5.5.2. Written and properly signed records of each audit shall be maintained. Each audit report shall include the following:

5.5.2.1. Date of the audit(s)

5.5.2.2. Person(s) performing the audit

5.5.2.3. Phase(s) or segment(s) of the study audited including the USDA and internal SOPs used as a basis for the audit

5.5.2.4. Observations, findings, and problems

5.5.2.5. Recommendations and suggested corrective actions

5.5.2.6. Any scheduled date for re-auditing

5.5.3. The audit report shall be distributed to the Administrative Manager and TPM. Audit reports shall be made available for inspection to authorized employees or duly designated representatives of USDA/AMS.

5.6. Proficiency Testing (PT) Program

The QAU shall review USDA PT Reports and submit comments on their laboratory's performance to the Administrative Manager, the TPM, and the Technical Director. The comments shall include recommendations as necessary to improve performance.

5.7. Deviation(s) from Program Plan and SOPs

The QAU shall assure that any deviations from approved plans or SOPs were properly authorized and documented.

5.8. QA SOPs

The responsibilities and procedures applicable to the QAU, the records maintained by the QAU, and the method of indexing such records shall be in writing and shall be maintained.

5.9. USDA Access to Records

An authorized employee or duly designated representative of USDA/AMS shall have access to the written procedures established per SOP MDP-ADMIN-07 and may request laboratory management to certify that audits are being implemented, performed, documented, and followed up in accordance with section 5.5 of this SOP.

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ELECTRONICALLY REPRODUCED SIGNATURES

Revision 01 May 2006 Monitoring Programs Office

- 5.2 modified to allow electronic copies to suffice
- Adjusted text for clarification
- Modified format for consistency with other SOPs

Original May 2003 Monitoring Programs Office

- Established QAU requirements for MDP